

REMARKS

Reconsideration of this application and reexamination of the claims in view of the amendments and remarks presented herein are respectfully requested.

Claims 87-99 and 101-147 are being cancelled without prejudice to, or disclaimer of, the subject matter recited therein. Claims 1, 78, 80, and 81 have been amended. Applicants reserve the right to prosecute claims directed to the subject matter of the cancelled claims in one or more continuation and/or divisional applications. With entry of this amendment claims 1, 75-86, and 100 are pending.

Applicants have amended claims 1, 78, 80, and 81 to make the claims even more clear. The amendments find support throughout the application as filed, such as in claim 1, for example, and do not add new matter.

Claim 1 is Pending

The Office Action Summary sheet incorrectly indicates that claim 1 is not pending in this application. However, claim 1 has never been cancelled and is pending. When this application was filed, the transmittal letter requested cancellation of claims 2-74. Claim 1 was not cancelled. Claims 75-147 were added to the application by a Preliminary Amendment filed June 19, 2002. Many of the added claims depend from claim 1, which remained pending. Claim 1 was then amended in an Amendment and Response to Restriction Requirement and Election of Species Requirements, filed July 17, 2003, and remained pending. Applicants also noted in that Response that, although the Office failed to address claim 1 in the Restriction Requirement, claim 1 was pending and should be part of elected Group I, which includes many claims that depend from claim 1. In view of these circumstances Applicants assume that the omission of claim 1

from the listing of pending claims on the Office Action Summary was an unintentional oversight.

Claim Objections

Claims 116-118 were objected to as drawn to non-elected subject matter. Applicants have cancelled claims 116-118 herein, thus obviating the basis for this rejection.

Priority

When this application was filed, the transmittal letter indicated that the application is a continuation of (then) pending prior Application No. 09/485,536, filed February 14, 2000 ("the '536 application"), which was expressly incorporated into the instant application by reference. (A copy of the transmittal letter for the instant application is attached hereto as Exhibit A.) The '536 application is a national stage application of PCT/FR98/01813, which has an international filing date of August 14, 1998, and was published on February 25, 1999, as WO 99/09186. (Copies of the transmittal letter for the '536 application and the face page of WO 99/09186, which was filed together with the '536 application, are attached hereto as Exhibit B.) Because PCT/FR98/01813 designated the United States, it has the same effect, from its international filing date, of a national application filed in the United States. 35 U.S.C. § 363. Thus, the reference to the '536 application in the transmittal letter filing the instant application was also a reference to PCT/FR98/01813, which is the same application. Under § 363, the filing date of the '536 application is the international filing date, i.e., August 14, 1998.

(February 14, 2000, is the date that all requirements for the national stage were met.) This is within one year of the filing date of FR 97/10,404 and FR 97/11,325, to which Applicants claimed priority in the '536 application transmittal letter (Exhibit B), and in the instant application by virtue of the incorporation of the '536 application (including the WO cover page) by reference. Applicants note that priority to FR 97/10,404 and FR 97/11,325, was also claimed in the Declaration, which was filed in the instant application on May 2, 2002. (A copy of the Declaration, a Petition for Filing Declaration Under 37 C.F.R. § 1.47 - Non-Signing Inventor, and Declaration in Accordance With 37 C.F.R. § 1.47(a), all filed together on May 2, 2002, are attached hereto as Exhibit C.)

Applicants submit that they have complied with the requirements for claiming priority to PCT/FR98/01813, FR 97/10,404, and FR 97/11,325. Applicants have amended the first paragraph of the specification herein to include a reference to the priority that was claimed. No new matter is introduced by this amendment.

Claim Rejections Under 35 U.S.C. § 102

Claims 1, 75-86, 100, and 116-118 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Gicquel et al., FR 2 767 336 ("FR '336"). The publication date of FR 2 767 336 is February 19, 1999. This is *after* the international filing date of PCT/FR98/01813, which, as described above, is the filing date of the '536 application, to which the instant application claims priority under 35 U.S.C. § 120. Under § 363 this international filing date is the filing date of the '563 application, and under § 120 it is the effective filing date of the instant application. Thus, FR '336 is not prior art to the instant

application. In view of these circumstances, Applicants ask that the Examiner withdraw the rejection for anticipation over FR '336.

Claims 1, 75, 76, 79, 81-84 and 100 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by either Gicquel et al. (US 6,248,581 B1) ("the '581 patent") or Gicquel et al. (WO 96/07745) ("WO '745"). As described above, the effective United States filing date of the instant application is the August 14, 1998, filing date of PCT/FR98/01813. Thus, the '581 patent is not prior art under 35 U.S.C. § 102(b) to the instant application. In view of these circumstances, Applicants ask that the Examiner withdraw the rejection for anticipation over the '581 patent.

The invention of the present claims generally provides a way to identify mycobacterium sequences coding for polypeptides, which are exported and/or secreted and, which can be induced or repressed during infection (Application at page 8, lines 16-24 and 27-32; page 12, lines 14-20; and page 15, lines 9-15). The identification of these sequences provides a basis for selecting good candidate vaccines and for understanding the interaction between mycobacteria and their host cells (see application at page 7, lines 27-33). In order to identify such mycobacteria sequences, the inventors have constructed a recombinant vector comprising both a sequence coding for an export and/or secretion marker and a sequence coding for a marker for the activity of promoters, this second sequence being inserted with its initiation codon in order to be expressed along with the export and/or secretion sequence, such as a synthetic operon (see Application at page 73, lines 1-3). For example, in Example 2 of the application, the polypeptide DP 428 is shown to be strongly induced during

Mycobacterium phagocytosis when using recombinant *Mycobacterium tuberculosis* transformed by the recombinant vector “pJVED” of the present invention.

Thus, the rejected claims recite a “vector that . . . contains: . . . 3) a reporter cassette comprising: . . . c) a coding nucleotide sequence, which is derived from a gene encoding a protein expression, export and/or secretion marker, said nucleotide sequence lacking its initiation codon and its regulatory sequences, **and** d) a coding nucleotide sequence derived from a gene encoding a marker for the activity of promoters, which are contained in the same fragment, said nucleotide sequence having its initiation codon.” (Emphasis added.)

In contrast to the invention of the rejected claims, WO '745 generally concerns the identification of Mycobacterial sequences coding for polypeptides, which are exported and/or secreted (see Example I), or the evaluation of different expression promoters in Mycobacteria (see Example III). As shown in these Examples I and III, the identification of these exported and/or secreted sequences or of these expression promoters is carried out in isolated mycobacteria and not in a “Mycobacterial context” (that is to say in presence of macrophages).

None of the vectors in WO '745 contain a coding nucleotide sequence, which is derived from a gene encoding a protein expression, export and/or secretion marker, where the nucleotide sequence lacks its initiation codon and its regulatory sequences, **and** a coding nucleotide sequence derived from a gene encoding a marker for the activity of promoters, which are contained in the same fragment, and where the nucleotide sequence has its initiation codon. Instead, the vectors of WO '745 comprise a sequence lacking its initiation codon, coding for an export and/or secretion marker,

such as truncated phoA (see vector pJEM 11 in Example I); or a sequence lacking its initiation codon coding for a marker of activity of promoter, such as truncated LacZ (see vectors pJEM 12, 13 and 14 in Example III). Because of this deficiency, WO '745 fails to disclose every element of the claimed invention and can not anticipate the rejected claims for this reason. See *Verdegaal Bros v. Union Oil Co. of Calif.*, 814 F.2d 628, 631 (Fed. Cir. 1987) ("A claim is anticipated only if each and every element as set forth in the claim is found either expressly or inherently in a single prior art reference."); M.P.E.P. § 2131. In view of these circumstances, Applicants request that the Examiner withdraw the rejection for anticipation over WO '745.

Double Patenting

Claims 1, 75, 76, and 79 were rejected under the judicially created doctrine of obviousness-type double patenting as being allegedly unpatentable over claims 5 and 6 of U.S. Patent No. 6,248,581. (Office Action at pages 3-5.) According to the Office, "[a]lthough the conflicting claims are not identical, they are not patentably distinct from each other because claims 1 and 79 are generic to the expression vector recited in claims 5 and 6 of U.S. Patent No. 6,248,581." (Office Action at pages 3-5.) Applicants respectfully traverse.

Claim 1, and claims 75, 76, and 79 as they depend from claim 1, recite a "vector that . . . contains: . . . 3) a reporter cassette comprising: . . . c) a coding nucleotide sequence, which is derived from a gene encoding a protein expression, export and/or secretion marker, said nucleotide sequence lacking its initiation codon and its regulatory sequences, and d) a coding nucleotide sequence derived from a gene encoding a

marker for the activity of promoters, which are contained in the same fragment, said nucleotide sequence having its initiation codon.” (Emphasis added.) This combination of elements is not present in claims 5 and 6 of U.S. Patent No. 6,248,581. Accordingly, contrary to the Office’s assertion, claims 1 and 79 are not generic to claims 5 and 6 of U.S. Patent No. 6,248,581.

When, as here, the Office asserts that a claim in an application is an obvious variant of a claim in an issued patent, and the pending application was filed after the application that matured into the patent, the issue is whether the invention defined in a claim of the application is an obvious variation of the invention defined in a claim of the issued patent. M.P.E.P. 804(II)(B)(1). Obviousness in this context is assessed based on a one-way test, considering the pending claims in view of the issued claims. M.P.E.P. 804(II)(B)(1). The remaining disclosure of the patent may not be used as prior art. M.P.E.P. 804(II)(B)(1). An obviousness-type double patenting rejection is analogous to a rejection under 35 U.S.C. § 103(a), and the elements of the analysis are the same. See M.P.E.P. 804(II)(B)(1).

Neither claims 5 nor 6 of the ‘581 patent recite a “vector that . . . contains: . . . 3) a reporter cassette comprising: . . . c) a coding nucleotide sequence, which is derived from a gene encoding a protein expression, export and/or secretion marker, said nucleotide sequence lacking its initiation codon and its regulatory sequences, **and** d) a coding nucleotide sequence derived from a gene encoding a marker for the activity of promoters, which are contained in the same fragment, said nucleotide sequence having its initiation codon.” Applicants submit that this combination of elements is not present in the ‘581 patent claims, and that nothing in the prior art would have suggested or

motivated one skilled in the art to modify the '581 patent claims to arrive at the invention defined by Applicants' pending claims, which all require this combination of elements. Indeed, the Office has not pointed to any such disclosure, suggestion, or motivation.

For this reason, claims 1, 75, 76, and 79 are nonobvious over claims 5 and 6 of the '581 patent, and an obviousness-type double patenting rejection is inappropriate. Accordingly, Applicants request that the Examiner withdraw the rejection for obviousness-type double patenting.

Claim Rejections Under 35 U.S.C. § 112

Claims 1, 75-86, 100, and 116-118 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. (Office Action at pages 7-8.) The Office based its conclusion on its assertion that the language "recombinant screening, cloning **and/or** expression vector" renders it unclear what activity the claimed vectors have. (Office Action at page 8; emphasis added.) Applicants disagree that the language rendered the claims unclear. However, to expedite prosecution of the application Applicants have amended claim 1 to recite "[r]ecombinant screening, cloning, ~~and/or~~ or expression vector that replicates in mycobacteria." Applicants note that this language makes clear that the claimed vectors possess at least one of these attributes. This language also makes clear that the claim encompasses vectors that simultaneously possess more than one of these attributes.

Regarding claim 81, the Office asserted that the recitation of "and/or" at many places in the claim "renders it unclear as to whether the all the clauses are limitations to

the claim, some of the clauses are limitations to the claim or whether none are limitations to the claims.” (Office Action at page 8.) In response, Applicants have added a coma to the claim to make it even more clear. Applicants submit that, consistent with the clear meaning of “and/or”, each element separated by an “and/or” may be present or absent. For example, the vector may comprise a nucleic acid sequence of a mycobacterium in which detection is carried out of a polypeptide capable of being exported and secreted. As another example, the vector may comprise a nucleic acid sequence of a mycobacterium in which detection is carried out of a polypeptide capable of being exported or secreted. Applicants respectfully submit that the claim is clear. If the Examiner disagrees, Applicants invite the Examiner to contact the undersigned to discuss the possibility of adding multiple claims to the application directed to the various sub-embodiments encompassed by claim 81.

In view of the amendments to the claims and the above comments, Applicants submit that the rejection of claims 1, 75-86, 100, and 116-118 for alleged indefiniteness may be properly withdrawn and request that the Examiner do so.

Conclusion

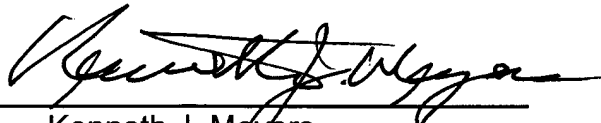
In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

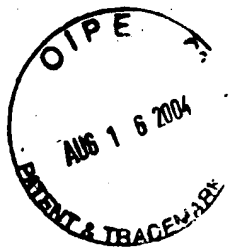
Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: August 16, 2004

By: 
Kenneth J. Meyers
Reg. No. 25,146

Attachments: Exhibits A-C



PATENT
Attorney's Docket Number: 03715.0062-01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

ASSISTANT COMMISSIONER FOR PATENTS
Washington, D.C. 20231

Prior Application: Art Unit: **Not Assigned**
Examiner: **L. Smith**

SIR: This is a request for filing a

■ Continuation □ Continuation-in-Part □ Divisional Application under 37 C.F.R. § 1.53(b) of pending prior application Serial No. 09/485,536 filed February 14, 2000 of Brigitte GICQUEL et al. for POLYPEPTIDE NUCLEIC SEQUENCES EXPORTED FROM MYCOBACTERIA, VECTORS COMPRISING SAME, AND USES FOR DIAGNOSING AND PREVENTING TUBERCULOSIS.

1. ■ Enclosed is a complete copy of the prior application, including the drawings, as originally filed. I hereby verify that the attached papers are a true copy of prior application Serial No. 09/485,536 as originally filed on February 14, 2000, which is incorporated herein by reference.
2. □ Enclosed is a substitute specification under 37 C.F.R. § 1.125.
3. □ Enclosed is a Request for Non-Publication of Application and Certification Under 35 U.S.C. § 1.22(b)(2)(B)(i).
4. ■ Cancel Claims 2-74.
5. □ A Preliminary Amendment is enclosed.
6. ■ The filing fee is calculated on the basis of the claims existing in the prior application as amended at 4 and 5 above.

LAW OFFICES

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FARABOW, GARRETT,
& DUNNER, L.L.P.
1300 I STREET, N. W.
WASHINGTON, DC 20005
202-408-4000

Basic Application Filing Fee					\$710	\$ 710.00
	Number of Claims		Basic	Extra Claims		
Total Claims	1	-	20	0	x \$18	710.00
Independent Claims	1	-	3	0	x \$80	
[] Presentation of Multiple Dep. Claim(s)					+\$270	
					Subtotal	\$ 710.00
					Reduction by ½ if small entity	-
					TOTAL APPLICATION FILING FEE	\$ 710.00

7. ■ A check in the amount of \$710.00 to cover the filing fee is enclosed.
8. ■ The Commissioner is hereby authorized to charge any fees which may be required including fees due under 37 C.F.R. § 1.16 and any other fees due under 37 C.F.R. § 1.17, or credit any overpayment during the pendency of this application to Deposit Account No. 06-0916.
9. ■ Amend the specification by inserting before the first line, the sentence:
 --This is a continuation of application Serial No. 09/485,536, filed February 14, 2000, which is incorporated herein by reference.--
10. □ New formal drawings are enclosed.
11. □ The prior application is assigned of record to: _____.
12. □ Priority of application Serial No. _____, filed on _____ in _____ (country) is claimed under 35 U.S.C. § 119. A certified copy
 □ is enclosed or □ is on file in the prior application.
13. □ A verified statement claiming small entity status
 □ is enclosed or □ is on file in the prior application.
14. ■ The power of attorney in the prior application is to at least one of the following: FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P., Douglas B. Henderson, Reg. No. 20,291; Ford F. Farabow, Jr., Reg.

LAW OFFICES

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No. 20,630; Arthur S. Garrett, Reg. No. 20,338; Donald R. Dunner, Reg. No. 19,073; Brian G. Brunsvold, Reg. No. 22,593; Tipton D. Jennings, IV, Reg. No. 20,645; Jerry D. Voight, Reg. No. 23,020; Laurence R. Hefter, Reg. No. 20,827; Kenneth E. Payne, Reg. No. 23,098; Herbert H. Mintz, Reg. No. 26,691; C. Larry O'Rourke, Reg. No. 26,014; Albert J. Santorelli, Reg. No. 22,610; Michael C. Elmer, Reg. No. 25,857; Richard H. Smith, Reg. No. 20,609; Stephen L. Peterson, Reg. No. 26,325; John M. Romary, Reg. No. 26,331; Bruce C. Zotter, Reg. No. 27,680; Dennis P. O'Reilley, Reg. No. 27,932; Allen M. Sokal, Reg. No. 26,695; Robert D. Bajefsky, Reg. No. 25,387; Richard L. Stroup, Reg. No. 28,478; David W. Hill, Reg. No. 28,220; Thomas L. Irving, Reg. No. 28,619; Charles E. Lipsey, Reg. No. 28,165; Thomas W. Winland, Reg. No. 27,605; Basil J. Lewris, Reg. No. 28,818; Martin I. Fuchs, Reg. No. 28,508; E. Robert Yoches, Reg. No. 30,120; Barry W. Graham, Reg. No. 29,924; Susan Haberman Griffen, Reg. No. 30,907; Richard B. Racine, Reg. No. 30,415; Thomas H. Jenkins, Reg. No. 30,857; Robert E. Converse, Jr., Reg. No. 27,432; Clair X. Mullen, Jr., Reg. No. 20,348; Christopher P. Foley, Reg. No. 31,354; John C. Paul, Reg. No. 30,413; David M. Kelly, Reg. No. 30,953; Kenneth J. Meyers, Reg. No. 25,146; Carol P. Einaudi, Reg. No. 32,220; Walter Y. Boyd, Jr., Reg. No. 31,738; Steven M. Anzalone, Reg. No. 32,095; Jean B. Fordis, Reg. No. 32,984; Roger D. Taylor, Reg. 28,992; Barbara C. McCurdy, Reg. No. 32,120; James K. Hammond, Reg. No. 31,964; Richard V. Burgujian, Reg. No. 31,744; J. Michael Jakes, Reg. No. 32,824; Thomas W. Banks, Reg. No. 32,719; Christopher P. Isaac, Reg. No. 32,616; Bryan C. Diner, Reg. No. 32,409; M. Paul Barker, Reg. No. 32,013; Andrew Chanhon Sonu, Reg. No. 33,457; David S. Forman, Reg. No. 33,694; Vincent P. Kovalick, Reg. No. 32,867; James W. Edmondson, Reg. No. 33,871; Michael R. McGurk, Reg. No. 32,045; Joann M. Neth, Reg. No. 36,363; Gerson S. Panitch, Reg. No. 33,751; Cheri M. Taylor, Reg. No. 33,216; Charles E. Van Horn, Reg. No. 40,266; Linda A. Wadler, Reg. No. 33,218; Jeffrey A. Berkowitz, Reg. No. 36,743; Michael R. Kelly, Reg. No. 33, 921; James B. Monroe, Reg. No. 33,971; Doris Johnson Hines, Reg. No. 34,629; Allen R. Jensen, Reg. No. 28,224; Lori Ann Johnson, Reg. No. 34,498; and David A. Manspeizer, Reg. No. 37,540.

15. ☐ The power appears in the original declaration of the prior application.
16. ☐ Since the power does not appear in the original declaration, a copy of the power in the prior application is enclosed.

LAW OFFICES

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202-408-4000

17. ■ This application is being filed under the provisions of 37 C.F.R. § 1.53(f). Applicants await notification from the Patent and Trademark Office of the time set for filing the Declaration.
18. ■ Please address all correspondence to FINNEGAN, HENDERSON, FARABOW, GARRETT and DUNNER, L.L.P., 1300 I Street, N.W., Washington, D.C. 20005-3315, **Customer Number 22,852.**
19. □ Recognize as associate attorney _____
(name, address & Reg. No.)
20. □ Also enclosed is _____

PETITION FOR EXTENSION. If any extension of time is necessary for the filing of this application, including any extension in the parent application, Serial No. 09/485,536, filed February 14, 2000, for the purpose of maintaining copendency between the parent application and this application, and such extension has not otherwise been requested, such an extension is hereby requested, and the Commissioner is authorized to charge necessary fees for such an extension to our Deposit Account No. 06-0916. A duplicate copy of this paper is enclosed for use in charging the deposit account.

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

By: Matthew T. Latimer
Matthew T. Latimer
Reg. No. 44,024

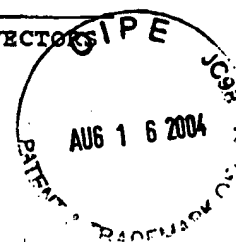
Date: May 16, 2001

TRANSMITTAL LETTER TO THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A FILING UNDER 35 U.S.C. 371

Attorney's Docket Number
03715.0062
U.S. Application No.

International Application. No. PCT/FR98/01813	International Filing Date August 14, 1998	Priority Date Claimed August 14, 1997 Sept. 11, 1997
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Title of Invention: POLYPEPTIDE NUCLEIC SEQUENCES EXPORTED FROM MYCOBACTERIA, VECTORS
COMPRISING SAME AND USES FOR DIAGNOSING AND PREVENTING
TUBERCULOSIS



Applicant(s) For DO/EO/US: GICQUEL, Brigitte et al.

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a FIRST submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371.
3. ☐ This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4. ☒ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
 - a. ☐ is transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☒ has been transmitted by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☒ A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
 - a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☐ have been transmitted by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☒ have not been made and will not be made.
8. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

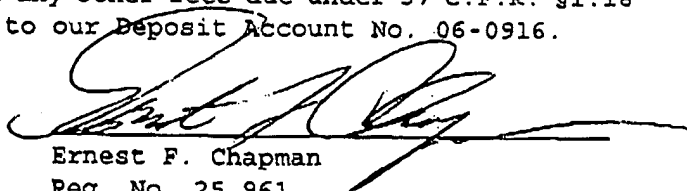
Items 11. to 16. below concern other document(s) or information included:

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☐ A FIRST preliminary amendment.
☐ A SECOND or SUBSEQUENT preliminary amendment.
14. ☐ A substitute specification.
15. ☐ A change of power of attorney and/or address letter.
16. ☐ Other items or information:
 - a. ☐ Verified Small Entity Statement.
 - b. ☐ Copy of Notification of Missing Requirements.

17. [X] The following fees are submitted:	CALCULATIONS			
Basic National Fee (37 CFR 1.492(a)(1)-(5)):				
Search Report has been prepared by the EPO or JPO.....	\$840.00			
International preliminary examination fee paid to USPTO (37 CFR 1.482).....	\$670.00			
No international preliminary examination fee paid to USPTO (37 CFR 1.482) but international search fee paid to USPTO (37 CFR 1.445(a)(2)).....	\$690.00			
Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO.....	\$970.00			
International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(1)-(4).....	\$ 96.00			
ENTER APPROPRIATE BASIC FEE AMOUNT =	\$ 840.00			
Surcharge of \$130.00 for furnishing the oath or declaration later than [] 20 [] 30 months from the earliest claimed priority date (37 CFR 1.492(e)).	\$			
Claims	Number Filed	Number Extra	Rate	
Total Claims	74-20=	54	X \$18.00	\$ 972
Independent Claims	5 - 3=	3	X \$78.00	\$ 156
Multiple dependent claim(s) (if applicable)			+\$260.00	\$
TOTAL OF ABOVE CALCULATIONS =				\$ 1,968
Reduction by 1/2 for filing by small entity, if applicable. Verified Small Entity statement must also be filed. (Note 37 CFR 1.9, 1.27, 1.28)				\$
SUBTOTAL =				\$
Processing fee of \$130.00 for furnishing the English translation later than [] 20 [] 30 months from the earliest claimed priority date (37 CFR 1.492(f)).				\$
TOTAL NATIONAL FEE =				\$ 1,968
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31).				\$
\$40.00 per property +				\$
TOTAL FEES ENCLOSED =				\$
Amount to be refunded				\$
charged				\$
a. [] A check in the amount of \$_____ to cover the above fees is enclosed.				
b. [X] Please charge my Deposit Account No. 06-0916 in the amount of \$1,968 to cover the above fees. A duplicate copy of this sheet is enclosed.				
c. [X] The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 06-0916. A duplicate copy of this sheet is enclosed.				

The Commissioner is hereby authorized to charge any other fees due under 37 C.F.R. §1.16 or §1.17 during the pendency of this application to our Deposit Account No. 06-0916.

SEND ALL CORRESPONDENCE TO:
Finnegan, Henderson, Farabow
Garrett & Dunner, L.L.P.
1300 I Street, N.W.
Washington, D.C. 20005-3315
KJM/FPD/cm

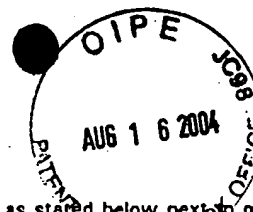

Ernest F. Chapman
Reg. No. 25,961

Submitted: February 14, 2000

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International patent classification⁶: C12N 15/74, 15/31, C07K 14/35, A61K 48/00, 39/04, C07K 19/00, C12Q 1/68, C07K 16/12, G01N 33/50, 33/53 // C12N 15/52, 15/65	A2	(11) International publication number: WO 99/09186 (43) International publication date: 25 February 1999 (25.02.99)
(21) International application number: PCT/FR98/01813 (22) International filing date: 14 August 1998 (14.08.98) (30) Data relating to the priority: 97/10,404 14 August 1997 (14.08.97) FR 97/11,325 11 September 1997 (11.09.97) FR (71) Applicant (for all designated States except US): INSTITUT PASTEUR [FR/FR]; 28, rue du Docteur Roux, F-75015 Paris (FR). (72) Inventors; and (75) Inventors/Applicants (US only): GICQUEL, Brigitte [FR/FR]; 8, rue Daguerre, F-75014 Paris (FR). PORTNOÏ, Denis [FR/FR]; 7, rue Simon Lefranc, F-75004 Paris (FR). LIM, Eng-Mong [KH/FR]; 20, rue Georges Pitard, F-75015 Paris (FR). PELICIC, Vladimir [FR/FR]; 28, rue de Chateaudun, F-75009 Paris (FR). GUIGUENO, Agnès [FR/FR]; 26-28, rue Gambetta, F-62026 Arras (FR). GOGUET DE LA SALMONIERE, Yves [FR/FR]; 30, rue Lourmel, F-75015 Paris (FR). (74) Representatives: MARTIN, Jean-Jacques etc.; Cabinet Regimbeau, 26, avenue Kléber, F-75116 Paris (FR).		(81) Designated states: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, HR, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO Patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian Patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European Patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI Patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published <i>Without the International Search Report and to be republished once the report has been received. With details relating to biological material which has been filed, supplied in accordance with rule 13a, separately, and not with the description</i>
As printed		
(54) Title: POLYPEPTIDE NUCLEIC SEQUENCES EXPORTED FROM MYCOBACTERIA, VECTORS COMPRISING SAME AND USES FOR DIAGNOSING AND PREVENTING TUBERCULOSIS (54) Titre: SEQUENCES NUCLEIQUES DE POLYPEPTIDES EXPORTEES DE MYCOBACTERIES, VECTEURS LES COMPRENANT ET APPLICATIONS AU DIAGNOSTIC ET A LA PREVENTION DE LA TUBERCULOSE (57) Abstract The invention concerns recombinant vectors replicated in mycobacteria, a set of sequences coding for exported polypeptides detected by fusion with alkaline phosphatase, in particular one polypeptide, called DP428, of about 12 kD corresponding to an exported protein found in mycobacteria belonging to the <i>Mycobacterium tuberculosis</i> complex. The invention also concerns methods and kits for detecting in vitro the presence of a mycobacterium and in particular a mycobacterium belonging to the <i>Mycobacterium tuberculosis</i> complex in a biological sample using said polypeptides, their fragments or polynucleotides coding for the latter. The invention also concerns immunogenic or vaccine compositions for preventing and/or treating infections caused by mycobacteria and in particular a mycobacterium belonging to said complex, particularly tuberculosis. (57) Abrégé L'invention a pour objet des vecteurs recombinants se répliquant chez les mycobactéries, un ensemble de séquences codant pour des polypeptides exportés détectés par des fusions avec la phosphatase alcaline, notamment un polypeptide, dénommé DP428, d'environ 12kD correspondant à une protéine exportée retrouvée dans les mycobactéries appartenant au complexe de <i>Mycobacterium tuberculosis</i> . L'invention concerne également des procédés et des kits de détection <i>in vitro</i> de la présence d'une mycobactérie et en particulier une mycobactérie appartenant au complexe de <i>Mycobacterium tuberculosis</i> dans un échantillon biologique utilisant lesdits polypeptides, leurs fragments ou des polynucléotides codant pour ces derniers. L'invention vise des compositions immunogènes ou vaccins pour la prévention et/ou le traitement d'infections provoquées par des mycobactéries et en particulier une mycobactérie appartenant audit complexe, en particulier la tuberculose.		

DECLARATION AND POWER OF ATTORNEY



As a below named inventor, I hereby declare that: my residence, post office address and citizenship are as stated below next to my name; I believe I am the original, first, and sole inventor (if only one name is listed below) or an original, first, and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

the specification of which ☐ is attached and/or ☒ was filed on August 14, 1998 as United States Application Serial No. or PCT International Application No. PCT/FR98/01813 and was amended on (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above, I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR § 1.56.

I hereby claim foreign priority benefits under 35 U.S.C. § 119(a)-(d) or § 365(b) of any foreign application(s) for patent or inventor's certificate or § 365(e) of any PCT International application(s) designating at least one country other than the United States, listed below and have also identified below, any foreign application(s) for patent or inventor's certificate, or any PCT International application(s) having a filing date before that of the application(s) of which priority is claimed:

Country	Application Number	Date of Filing	Priority Claimed Under 35 U.S.C. 119	
France	97 10404	August 14, 1997	<input type="checkbox"/> YES	<input type="checkbox"/> NO
France	97 11325	September 11, 1997	<input type="checkbox"/> YES	<input type="checkbox"/> NO

I hereby claim the benefit under 35 U.S.C. § 119(e) of any United States provisional application(s) listed below:

Application Number	Date of Filing

I hereby claim the benefit under 35 U.S.C. § 120 of any United States application(s) or § 365(c) of any PCT International application(s) designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application(s) in the manner provided by the first paragraph of 35 U.S.C. § 112, I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR § 1.56 which became available between the filing date of the prior application(s) and the national or PCT International filing date of this application:

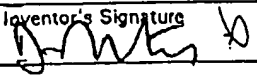
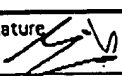
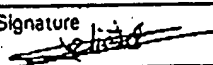
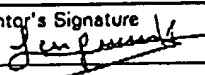

Application Number	Date of Filing	Status (Patented, Pending, Abandoned)
PCT/FR98/01813	August 14, 1998	Pending

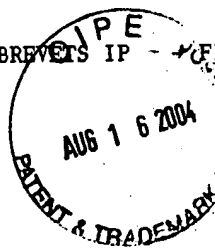
I hereby appoint the following attorney and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith: FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER L.L.P., Douglas B. Henderson, Reg. No. 20,291; Ford F. Farabow, Jr., Reg. No. 20,630; Arthur S. Garrett, Reg. No. 20,338; Donald R. Dunner, Reg. No. 19,073; Brian G. Brunsvold, Reg. No. 22,593; Tipton D. Jennings, IV, Reg. No. 20,645; Jerry D. Voight, Reg. No. 23,020; Laurence R. Hefter, Reg. No. 20,827; Kenneth E. Payne, Reg. No. 23,098; Herbert H. Mintz, Reg. No. 26,691; C. Larry O'Rourke, Reg. No. 26,014; Albert J. Santorelli, Reg. No. 22,610; Michael C. Elmer, Reg. No. 25,857; Richard H. Smith, Reg. No. 20,609; Stephen L. Peterson, Reg. No. 26,325; John M. Romary, Reg. No. 26,331; Bruce C. Zotter, Reg. No. 27,680; Dennis P. O'Reilly, Reg. No. 27,932; Allen M. Sokal, Reg. No. 26,695; Robert D. Bajelsky, Reg. No. 25,387; Richard L. Stroup, Reg. No. 28,478; David W. Hill, Reg. No. 28,220; Thomas L. Irving, Reg. No. 28,619; Charles E. Lipsey, Reg. No. 28,165; Thomas W. Winland, Reg. No. 27,605; Basil J. Lewis, Reg. No. 28,818; Martin I. Fuchs, Reg. No. 28,508; E. Robert Yoches, Reg. No. 30,120; Barry W. Graham, Reg. No. 29,924; Susan Haberman Griffen, Reg. No. 30,907; Richard B. Racine, Reg. No. 30,415; Thomas H. Jenkins, Reg. No. 30,857; Robert E. Converse, Jr., Reg. No. 27,432; Clair X. Mullen, Jr., Reg. No. 20,348; Christopher P. Foley, Reg. No. 31,354; John C. Paul, Reg. No. 30,413; Roger D. Taylor, Reg. No. 28,992; David M. Kelley, Reg. No. 30,953; Kenneth J. Meyers, Reg. No. 25,146; Carol P. Einaudi, Reg. No. 32,220; Walter Y. Boyd, Jr., Reg. No. 31,738; Steven M. Anzalone, Reg. No. 32,095; Jean B. Fordis, Reg. No. 32,984; Barbara C. McCurdy, Reg. No. 32,120; James K. Hammond, Reg. No. 31,964; Richard V. Burguijan, Reg. No. 31,744; Michael Jakes, Reg. No. 32,824; Dirk D. Thomas, Reg. No. 32,600; Thomas W. Banks, Reg. No. 32,719; Christopher P. Isaac, Reg. No. 32,616; Bryan C. Diner, Reg. No. 32,409; M. Paul Barker, Reg. No. 32,013; Andrew Chanho Sonu, Reg. No. 33,457; David S. Forman, Reg. No. 33,694; Vincent P. Kovalick, Reg. No. 32,867; James W. Edmondson, Reg. No. 33,871; Michael R. McGurk, Reg. No. 32,045; Joann M. Nath, Reg. No. 35,363; Gerson S. Panitch, Reg. No. 33,751; Cheri M. Taylor, Reg. No. 33,216; Charles E. Van Horn, Reg. No. 40,266; and Linda A. Wadler, Reg. No. 33,218; and Please address all correspondence to FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P. 1300 I Street, N.W. Washington, D.C. 20005, Telephone No. (202) 408-4000.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Full Name of First Inventor GICQUEL Brigitte	Inventor's Signature 	Date
Residence 8, rue Daguerre - 75014 PARIS - France	Citizenship FRENCH	
Post Office Address The same as residence		

Listing of Inventors Continued on Page 2 hereof. ☒ Yes ☐ No

Full Name of Second Inventor PORTNOÏ Denis	Inventor's Signature 	Date
Residence 7, rue Simon Lefranc - 75004 PARIS - FRANCE	Citizenship FRENCH	
Post Office Address The same as residence		
Full Name of Third Inventor LIM Eng-Mong	Inventor's Signature 	Date
Residence 20, rue Georges Pitard - 75015 PARIS - FRANCE	Citizenship CAMBODIAN	
Post Office Address The same as residence		
Full Name of Fourth Inventor PELICIC Vladimir	Inventor's Signature 	Date
Residence 28, rue de Chateaudun - 75009 PARIS - FRANCE	Citizenship FRENCH	
Post Office Address The same as residence		
Full Name of Fifth Inventor GUIGUENO Agnès	Inventor's Signature 	Date
Residence 26-28, rue Gambetta - 62026 ARRAS - FRANCE	Citizenship FRENCH	
Post Office Address The same as residence		
Full Name of Sixth Inventor GOGUET DE LA SALMONIERE Yves	Inventor's Signature 	Date
Residence 30, rue Lourmel - 75015 PARIS - FRANCE	Citizenship FRENCH	
Post Office Address The same as residence		
Full Name of Seventh Inventor	Inventor's Signature	Date
Residence	Citizenship	
Post Office Address		
Full Name of Eighth Inventor	Inventor's Signature	Date
Residence	Citizenship	
Post Office Address		
Full Name of Ninth Inventor	Inventor's Signature	Date
Residence	Citizenship	
Post Office Address		
Full Name of Tenth Inventor	Inventor's Signature	Date
Residence	Citizenship	
Post Office Address		
Full Name of Eleventh Inventor	Inventor's Signature	Date
Residence	Citizenship	
Post Office Address		



PATENT

Attorney Docket No. 03715-0062-01

Customer Number 22,852

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Brigitte GICQUEL et al.

Serial No.: 09/855,604

Group Art Unit: Not Yet Assigned

Filed: May 16, 2001

Examiner: Not Yet Assigned

For: POLYPEPTIDE NUCLEIC SEQUENCES EXPORTED FROM MYCOBACTERIA,
VECTORS COMPRISING SAME AND USES FOR DIAGNOSING AND
PREVENTING TUBERCULOSIS

Assistant Commissioner for Patents
Washington, DC 20231

Attention: **BOX MISSING PARTS**

Sir:

DECLARATION IN ACCORDANCE WITH 37 C.F.R. § 1.47(a)

I, Danielle Berneman, do hereby make the following declaration:

1. I am head of the Patents and Inventions Office of Institut Pasteur, one of the two Assignees of this patent application.
2. Institut Pasteur is responsible for prosecution of this patent application.
3. The invention described in this application was made by Brigitte Gicquel, Denis Portnoï, Eng-Mong Lim, Vladimir Pelicic, Agnès Guigeno, and Yves Goguet de la Salmonière.
4. The last known address of Mr. Goguet de la Salmonière is:

30 rue de Lourmel
75015 Paris
France
5. I am the person at Institut Pasteur who is responsible for ensuring that the inventors execute the Oath or Declaration for U.S. patent applications.

FINNEGAN
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1300 I Street, NW
Washington, DC 20005
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PATENT

Attorney Docket No. 03715-0062-01

Customer Number 22,852

6. I forwarded a package, including the entire application and an oath/declaration, to Mr. Goguet de la Salmonière at his last known address on February 7, 2002, for his review and execution.

7. I received from the French post the returned package, with "NHPAI" handwritten on the package. "NHPAI" stands for "N'Habite Plus à l'Adresse Indiquée," which translates into "does not live at the indicated address."

8. I am not aware of a new address for Mr. Goguet de la Salmonière.

9. Attached is a copy of the communication referred to in paragraph 6 (including an English translation), and two copies of the French post receipt, in different levels of darkness, so that the various writing on the receipt can be interpreted.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements might jeopardize the validity of the application or any patent issuing thereon.

Date: April 2nd 2002 By: 

Danielle Berneman
Head of Patents and Inventions Office
Institut Pasteur
28 Rue du Docteur Roux
75724 Paris Cedex 15
FRANCE

Danielle BERNEMAN
Chef du Service des Brevets
& Inventions



INSTITUT PASTEUR

25-28, rue du Docteur Roux
75724 Paris Cedex 15

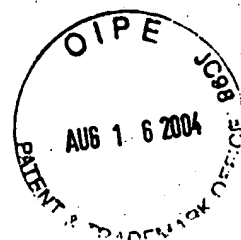
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202.408.4000
Fax 202.408.4400
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Paris,

- 7. FEVR 2002



INSTITUT PASTEUR

Service des Brevets et Inventions

Monsieur Yves GOGUET de la SALMONIERE
30 rue de Lourmel
75015 - PARIS

Lettre recommandée avec accusé réception

DB/EB/NC-02/0251

Objet : Banque génomique de Mycobacterium Tuberculosis
Invention GICQUEL et al
DI 97-25 et 98-31

Cher Monsieur,

Nous revenons vers vous concernant l'invention citée en objet et plus particulièrement concernant la demande US 855604 correspondant à la demande internationale PCT/FR98/01813 déposé le 14/08/1998.

Afin d'éviter la perte des droits attachés à cette invention, nous vous adressons sous ce pli :

- une copie du texte tel que déposé de la demande internationale,
- une copie du texte tel que déposé de la demande US 85560,
- un nouveau jeu de documents (cession CANADA et USA et déclaration) que je vous remercie de bien vouloir dater et signer.

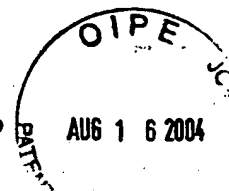
Ces documents devant être déposés devant les Offices concernés, au plus tard le 22 février 2002, je vous serais reconnaissante de bien vouloir me les retourner au plus tard le 19 février 2002.

Je vous prie de croire, Cher Monsieur, à l'assurance de ma considération distinguée.

Danielle BERNEMAN
Chef du Service des Brevets et Inventions

PJ : 3

Direction de la Valorisation Cc : B. Gicquel
et des Partenariats Industriels E. Bonnefoi



Paris, 7 February 2002

INSTITUT PASTEUR

Patents and Inventions Department

Monsieur Yves GOGUET de la SALMONIERE
30, rue de Lourmel
75015 PARIS

Registered letter with acknowledgment receipt

DB/EB/NC-02/0251

Object : Mycobacterium Tuberculosis genomic bank
Invention GICQUEL et al.
DI -25 and 98-31

Dear Sir,

We revert to you concerning the above-cited invention and more particularly concerning the patent application US 855604 corresponding to the international patent application PCT/FR/ filed on 08/14/1998.

In order to avoid the loss of rights attached to this invention, you will find herewith enclosed :

- a copy of the text as filed of the international patent application,
- a copy as filed of the US 85560 patent application,
- a new set of documents (USA and CANADA assignment and statement) and thank you to duly date and sign.

These documents must be filed before the concerned Patent Offices by February 22, 2002, I would be grateful to return them to me by February 19, 2002.

Yours faithfully.

Danielle BERNEMAN
Chief of the Patents and Inventions Department

P.J. : 3

Cc : B. Gicquel
E. Bonnefoi

INSTITUT PASTEUR

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ENVOI D'UN OBJET RECOMMANDÉ
AVEC AVIS DE DÉCHIFFREMENT
RA 8461 3819 7FR

DI 24.25 et 38.34

Tombura Yoco GOGUET de la SALMONIERE



RA 8461 3819 7FR

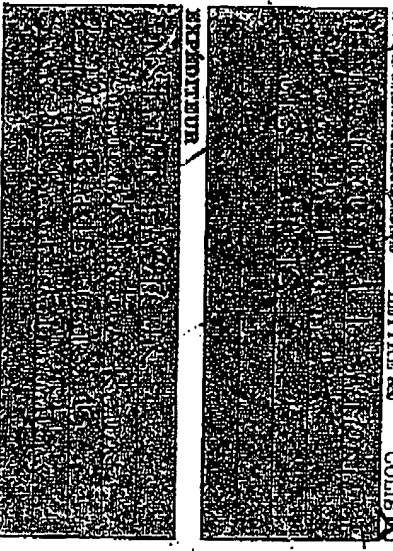
TARIFF DE RECOMMANDATION RI ☒ R ☐ R ☐

Classification de l'objet recommandé

Disposition de signature et de classement

Reçu	Reçu	Compte Rendu	Reçu de l'envoi
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DL 97.25 et 98.31

TAUX DE RECOMMANDATION R1 ☒ R2 ☐ R3 ☐
Taux réservé au service

Présentation le _____
Distribution le _____
Signature du destinataire _____

Date _____ Prix _____ Contre Remboursement _____ Nature de l'objet _____

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516-2 V8 - PFL 2 200 960



RA 8461 3819 7FR

Monsieur Yves GOGUET de la SALMONIÈRE

INSTITUT PASTEUR LETTRE ☒ COLIS ☒

M. Yves GOGUET de la SALMONIÈRE
30 rue de Lennel
75015 PARIS

EXPÉDITEUR

INSTITUT PASTEUR
25-28 rue du Docteur Roux
75724 PARIS Cedex 15
Service des Brevets et Inventions

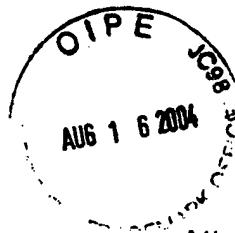
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RECOMMANDÉ AR



PATENT
Attorney Docket No. 03715-0062-01
Customer Number 22,852

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Brigitte GICQUEL et al.

Serial No.: 09/855,604

Filed: May 16, 2001

) Group Art Unit: Not Yet Assigned

) Examiner: Not Yet Assigned

For: POLYPEPTIDE NUCLEIC SEQUENCES EXPORTED FROM MYCOBACTERIA,
VECTORS COMPRISING SAME AND USES FOR DIAGNOSING AND
PREVENTING TUBERCULOSIS

Assistant Commissioner for Patents
Washington, DC 20231

Attention: **BOX MISSING PARTS**

Sir:

**PETITION FOR FILING DECLARATION
UNDER 37 C.F.R. § 1.47 - NON-SIGNING INVENTOR**

Applicants hereby petition that the attached Declaration, executed by inventors Brigitte Gicquel, Denis Portnoï, Eng-Mong Lim, Vladimir Pelicic, and Agnès Guigueno, be accepted by the U.S. Patent and Trademark Office on behalf of themselves and non-signing inventor Yves Goguet de la Salmonière. The required fee of \$130.00 under 37 C.F.R. § 1.17(i) is attached hereto.

The circumstances surrounding the inability to obtain inventor Yves Goguet de la Salmonière's signature on the attached Declaration, as well as inventor Goguet de la Salmonière's last known address, are set forth in the accompanying Declaration of Mme. Danielle Berneman, head of the Patents and Inventions Office of Institut Pasteur, Assignee of this invention.

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HENDERSON
FARABOW
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DUNNER LLP

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Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: May 2, 2002

By: Sean Myers-Payne
Sean Myers-Payne
Reg. No. 42,920
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